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The Drug-Price Express Runs Into a Wall

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With a clatter of stadium-style seats, several hundred drug stock analysts rushed from the crowded amphitheater in Merck (news/quote)'s gleaming $250 million headquarters in Whitehouse Station, N.J., on Dec. 12. Racing into the nearby atrium, they began feverishly contacting their trading desks on their cellphones and Blackberries to report a bombshell for investors.

Judy C. Lewent, the chief financial officer, had just told the analysts that Merck, a pillar of the pharmaceutical industry and one of its most consistently highly profitable companies, expected no growth in earnings in 2002. The analysts had been expecting 8 percent.

By the end of the trading day, Merck shares dropped 9.4 percent, or $6.29, to $60.70.

Like most other pharmaceutical companies, Merck has hit a wall of resistance to the practice of continually promoting new drugs, typically with higher prices, that are sometimes no better than older ones.

That practice worked well throughout the prosperous 1990's, when employers paid most or all the costs, patients felt no financial pain, and doctors, who write the prescriptions, had little reason to challenge the sales pitches. It didn't hurt that a number of the drugs introduced in those years were breakthrough therapies for widespread problems like high blood pressure, excessive cholesterol and depression.

In those days, when health insurance companies and employers tried to slow the cost spiral, the manufacturers outfoxed them with a system of rebates tied to sales volume — the more that a health care provider prescribed a particular drug, the greater the rebate — and an avalanche of television and print advertising aimed at consumers. The industry is spending about $2.5 billion on consumer advertising this year.

But as the economy slumps, and as consumers bear more of the costs of their treatments, the state governments, managed- care companies and employers who foot the bills are trying to clamp down on drug expenditures, which have jumped 92 percent in five years, to $116.9 billion, according to the Employee Benefit Research Institute. Some are banding together to buy in bulk and to demand greater volume discounts.

Others are refusing to buy new drugs that are more expensive but not much more effective than generic versions. And some are considering laws to limit what drug makers can charge.

"There's a lot of pushback," said Robert D. Reischauer, an economist who is president of the Urban Institute, a Washington research center. "Budget difficulties in the states, the rapid rise in health insurance premiums and now the economic downturn" seem to have changed the equation, said Dr. Reischauer, who is also a former director of the Congressional Budget Office.

Patricia Wilson, an independent pharmaceutical consultant who advises large companies on controlling drug costs, was more succinct. "Employers are like the man in the movie who yelled, `I'm mad as hell and I'm not going to take it any more,' " she said.

The announcement by Merck was the latest and most startling in a chain of disappointments for pharmaceutical companies, including Bristol-Myers Squibb (news/quote), Eli Lilly, Schering-Plough (news/quote) and Pharmacia (news/quote). Wall Street has reacted by pushing down drug share prices this year by 18 percent, on average, for the eight largest companies, while the Standard & Poor's 500-stock index has declined 13 percent, according to Neil Sweig, a drug analyst at Ryan Beck & Company (news/quote). Merck was down 36 percent this year, at Friday's close of $59.63.

The worldwide economic slowdown, reduced budgets for health care and pressures from states and insurers have contributed to "the most challenging period for the entire drug industry that I can recall during more than 25 years in it," said Fred Hassan, chief executive of Pharmacia.

Even the rosy picture painted last week by Henry A. McKinnell, the chief executive of Pfizer (news/quote), which is still reporting double-digit earnings growth, included a mention of growing pressures on the industry from frustrated employers, insurance companies and consumers.

"Confronted with escalating health expenditures, both payers and providers are seeking to cap the growth of their costs," Dr. McKinell said.

The power shift in health care may be just starting, but it is already affecting drug industry revenue. The sales growth of 8 of the 10 most heavily advertised drugs, nearly all of which have annual sales of more than $1 billion, slowed in the third quarter, compared with the period in 2000, according to IMS Health (news/quote), a drug research firm.

The eight were Prilosec, a heartburn drug; Celebrex and Vioxx, for arthritis; Paxil, an antidepressant; Claritin, Allegra and Flonase, for allergies; and Viagra, for erectile dysfunction. Only Zocor and Pravachol, two cholesterol treatments, gained momentum, and that was after Baycol, a similar drug with dangerous side effects, was withdrawn from the market.

Patricia Danzon, a professor at the Wharton School of the University of Pennsylvania who specializes in pharmaceuticals, said the drug companies' high rate of growth "is not sustainable in the long run."

The reason is simple. Drug makers' biggest customers have realized that they are big enough to affect sales unilaterally, and the rapid rise in spending on drugs makes it imperative for them to act. More than 40 states are trying to rein in drug costs, especially as their budgets have been battered by the economic slowdown.

"State Medicaid programs are being blown up," said Tom Scully, administrator of the federal Center for Medicare and Medicaid Services.

Florida received federal permission in September under the Medicaid law to use its power as a buyer to extract concessions from Pfizer, which agreed to pay for an education program in the state explaining the value of generics. Mr. Scully said Michigan, Maine and at least a dozen other states were also preparing to ask for similar permission.

Last year, Maine passed a law that threatened drug makers with price controls. Florida and Michigan have let the drug companies know that if they do not reduce their prices, their products will be excluded from preferred lists of drugs available under Medicaid, which covers the health care costs of the poor.

Many states have begun to join together in buying groups, aiming to become much bigger, more powerful purchasers so that they can extract greater discounts from the drug companies.

Arkansas and Florida are sending emissaries to tell doctors that low- cost generic drugs can often be just as safe and effective as heavily advertised expensive products for the same ailments. "Much of the information that physicians get on drugs comes from salesmen who are on commission," said Ray Hanley, director of the Medicaid program in Arkansas. "Our research shows that most people do not need those drugs that are advertised excessively."

The drug companies are resisting. Last year, the industry asked a federal court to stop Maine's new law, and after losing a round in appeals court, the drug companies are now appealing to the United States Supreme Court.

The Pharmaceutical Research and Manufacturers of America, the industry's trade group in Washington, has also filed a federal suit against Florida and a state suit against Michigan.

Alan Holmer, the president of the trade group, said programs like Florida's and Michigan's, which try to limit the drugs doctors prescribe, can harm patients.

"When states impose prior authorization requirements, it puts patients who are most in need at the back of the health care line," Mr. Holmer said. "We think that is wrong."

Hoping to eliminate the growing patchwork of state laws, the drug companies have also been lobbying hard in Washington to have federal legislators add prescription drug coverage to Medicare.

But the states are only part of the problem for drug companies. Managed-care companies, facing skyrocketing costs themselves and more pressure from their customers to keep rate increases down, are tightening enforcement of the lists of drugs for which they will provide a high level of coverage. That way, they hope to force doctors and consumers to stick to less expensive treatments when several drugs are effective for a disease.

Many managed-care companies — and many big companies that insure their own employees — are requiring employees to shoulder more of the cost of drugs, particularly expensive ones.

In more than one in three drug plans, patients now pay about $7 a prescription, on average, for generic drugs; $14 for brand-name drugs on a preferred list; and $29 for all other prescription medications, according to Deutsche Banc Alex. Brown. Some companies, including Chevron, now require employees to pay a percentage of the full price for all drugs, instead of a flat $7 or $29. Such changes give patients an economic incentive to choose the cheapest drug that can treat their conditions.

Other companies take different approaches in response to similar pressures. Verizon Communications (news/quote), which does not use the percentage co-payment method, still expects employees to shoulder some of the drug burden, and is taking steps to encourage the use of generics.

"We are focused on making sure that value is always delivered," said Bruce Taylor, director of benefits planning at Verizon. His company is concerned about the growth in its bill for prescription drugs — to $500 million this year, or 25 percent of the $2 billion it spends on health care for one million employees, retirees and their families. Such a percentage is typical of older industries with many retirees.

"Value always means using the least costly drug that is appropriate to the individual, so you always start with an appropriate generic," Mr. Taylor said. "But in some cases you may even add an expensive drug that a patient should be getting."

Last summer, Verizon leaned on its drug plan managers to ensure that people taking Prozac switched to the newly available generic version, fluoxetine.

Similarly, the company is checking on whether it can use the new generic version of Mevacor, an older cholesterol treatment.

"Clearly, people are getting more aware of the cost of drugs," said William W. McGuire, chief executive of UnitedHealth Group, which covers 17 million people. "There is probably greater awareness by consumers that there can be options among many drugs within a category," like the cholesterol-lowering drugs.

Some Blue Cross plans, like Empire Blue Cross and Blue Shield in New York and WellPoint Health Networks, based in California, intend to offer a new pricing category next year that could be even more expensive than current reimbursement levels. It may cover "life style" products like Viagra and Rogaine, a treatment for hair loss.

In Empire's version, patients would pay a percentage, possibly 20 percent of the full cost, in its new category, said Dr. Michael Stocker, its chief executive. Empire is also planning to offer small-business customers a new drug discount card next year that will cover only generic drugs. Employees would have to pay the full price for brand-name drugs.

"Two years ago, the entire increase in drug costs was borne by health insurance," said Leonard Schaeffer, the chairman of WellPoint. "Now for the first time, with these three-tier drug plans, Americans are understanding how expensive these drugs have become."

At the same time, WellPoint and other managed-care companies are pressing the drug companies not to use delaying tactics against the introduction of generic versions of their best-selling drugs once the patents on them expire. Generics already account for more than 40 percent of the prescriptions in many managed-care drug plans. The generics' importance should surge in the next five years as American patents expire on drugs with $35 billion in sales, about 28 percent percent of all United States drug sales. That will pose a major threat to drug industry profits.

A generic version of Prozac, the best-selling antidepressant, was introduced last August; next year, rival generic versions of that drug will come on the market, putting additional pressure on prices. General Motors (news/quote) alone expects to save $7 million on Prozac over the next three years by buying the generic version.

WellPoint has campaigned to have the federal Food and Drug Administration change the classification of Claritin and Allegra, two best-selling allergy drugs, so they can be bought without a prescription. That would put them in direct competition with cheaper, comparable over-the- counter antihistamines. The change was supported in a 19-to-4 vote by an F.D.A. advisory committee and is awaiting a decision by a new food and drug commissioner. President Bush has not yet filled that position.

Some economists and others contend that the drug industry's recent focus on trying to extend patent protection for its best-selling drugs may have hurt more than it helped because it distracted them from developing new drugs.

"They are not bringing out as many new truly innovative products, which signals that this industry is going to hit some rougher financial times in the next two to five years," said Stephen Schondelmeyer, an economist at the University of Minnesota.

Larry Feinberg, a partner in Oracle Partners, a health care hedge fund, said that in many respects, the "glory days are over" for the drug industry. For example, he said, the companies can no longer demand higher prices for new "me-too drugs" that are not superior to older products.

Many companies are now putting their main research efforts into seeking "clinical breakthrough products as opposed to me-too products," said David D. Halbert, chief executive of AdvancePCS (news/quote), one of the biggest pharmaceutical benefit management companies.

The drug companies say they are just trying to get the best medications to the people who need them.

"Setting up bureaucratic hurdles is not, in our view, the right way to manage prescription costs," Mr. Hassan of Pharmacia said. "There is a real and present health risk to patients if they are steered toward a cheaper, but less appropriate, product. It would be unfortunate to have physicians' judgments second- guessed by what inevitably will be a bureaucratic and potentially arbitrary prior-approval process."

Merck, the only manufacturer that now has its own managed drug plan unit, Merck-Medco, takes a different tack.

Acknowledging that generic drugs are forcing drug makers to compete on price, Raymond V. Gilmartin, Merck's chief executive, said earlier this year that it was up to the pharmaceutical companies to "demonstrate improvements in patient care, health outcomes, quality of life and cost effectiveness" to win a place on insurers' lists of preferred drugs.

As it happens, Merck's problems are closely tied to the pressures from buyers for generics. Since last summer, patents have expired on three Merck products — Vasotec, a heart drug; Pepcid, for heartburn; and Mevacor. Next spring, it expects to face generic competition for Prilosec, the best-selling ulcer treatment, which it sells with AstraZeneca (news/quote).

Health insurers like WellPoint Health Networks and employers like Verizon and General Motors are already planning to push their health plan members to stay with a generic version of Prilosec.

In the past, the managers have often promoted more expensive brand-name alternatives.

"When Prilosec, the best ulcer drug in the world, goes off patent, why substitute another?" said Barbara Ryan, a pharmaceutical analyst at Deutsche Banc Alex. Brown, who says growth in drug company profits is slowing.

Even more important for Merck, many health plans have balked at paying for Vioxx and Celebrex, a similar arthritis drug made by Pharmacia, except for a relatively small number of patients who cannot tolerate over-the-counter ibuprofen painkillers like Advil and Motrin, which cost one-tenth as much.

It did not help Vioxx when a study in the Journal of the American Medical Association in August said that drugs like it might increase the risk of heart attacks in some patients. Merck said that conclusion was unfounded.

But David W. Anstice, president of Merck's human drug sales unit, said the company had been successful for years despite the pressures from insurers and employers. The reason for Merck's current earnings problems "really is the patent expirations," he said.

The payers, of course, see the issue through the other end of the telescope. Health plans like WellPoint are refusing to add expensive new drugs to their preferred lists unless the manufacturers come up with data to show they are worth the money.

"The issue for us is to make health care affordable," said Rob Seidman, WellPoint's chief pharmacy officer. "The enemy is the obscene prices for new pharmaceuticals where the cost-to-value equation has not yet been proved."